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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,370	04/17/2001	Eugen Uhlmann	02481.1742	5783

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EXAMINER	
SIEW, JEFFREY	

ART UNIT	PAPER NUMBER
1637	14

DATE MAILED: 10/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/835,370	Applicant(s) UHLMANN ET AL.	
	Examiner Jeffrey Siew	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above claim(s) *16-19 and 23-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,20-23 and 31-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 & 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

2. The courtesy copies of I.D.S. filed 10/26/02 paper no. 4 and 1/22/02 paper no. 5 have been received and considered.

Drawings

3. The drawings filed 4/17/01 do not appear in the file wrapper. It is respectfully requested that courtesy copies be submitted. The response states that copies of drawings were resubmitted but could not located in the file.

Election/Restrictions

4. The response has reiterated their traversal of the restriction requirement filed 9/17/02 and requested rejoinder. The response has been fully considered and deemed not persuasive. The traversal is on the ground(s) that all the claims 1-85 are sufficiently related that the search one one group would encompass the subject matter for the remaining claims and no serious burden exists. This is not found persuasive because Group I product may be synthesized by a plurality of different methods such as using the chiral centers of each PNA derivative and forcing precipitation of a specific diasteroisomers by altering the solvent conditions without the method

hybridization and sequencing methods. The scope of search do not encompass the full subject matter of the other claims and would entail serious burden. Moreover, the groups are sufficiently distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-19 & 24-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 , 20,21 & 31-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulhmann et al (Nucleosides & Nucleotides vol. 16(5&6) pp. 603-608 1997).

Ulhmann et al teach polyamide nucleic acids that bind to complementary DNA and RNA with N-(2aminoethyl)glycine units (see whole document esp. page 603, 604 & 607 structures). They teach PNAs as antisense therapeutics and DNA diagnostics (see page 604). They teach synthesis from derivatives off solid support.(see page 604).

The claims in the broadest reasonable interpretation wherein n is zero and z' is zero and {poly} is Formula IIIA.

Regarding the 102 and 103 rejections based on the primary reference Ulhmann et al, the response states that Uhlmann does not teach a phosphoryl radical at N terminal and therefore does not anticipate the claims. However, the limitations of claims do not necessarily require a phosphoryl radical. Q may be hydroxyl or any amino acid derivative which reads broadly on Ulhmann et al's compound.

6. Claims 1-12, 21,31-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Breipohl et al (US6,046,306 April 4,2000).

Breipohl et al teach polyamide nucleic acids. They teach various labels that may be associated with PNA such biotin, fluorescein (see col. 5 lines 1-10).

The claims in the broadest reasonable interpretation wherein n is zero and z' is zero and {poly} is Formula IIIA.

Regarding the 102 and 103 rejections based on the primary reference Breipohl et al, the response states that Breipohl does not teach a phosphoryl radical at N terminal and therefore does not anticipate the claims. However, the limitations of claims do not necessarily require a phosphoryl radical. Q may be hydroxyl or any amino acid derivative which reads broadly on Breipohl et al's compound.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22 & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulhmann et al (Nucleosides & Nucleotides vol. 16(5&6) pp. 603-608 1997) in view of Weiler et al (NAR vol. 15 no. 14 pp. 2792-2799 1997).

The teachings of Ulhmann et al are described previously.

Ulhmann et al do not teach microarray supports.

Weiler et al teach the construction of PNA oligomer arrays for hybridization assays (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Weiler et al's teaching of microarrays to Ulhmann et al's PNA in order to construct oligonucleotide sensors. As Weiler et al states the PNA may be used in arrays because the PNA provide high thermal

stability and are instrumental for screening sequences (see page 2792-3). It would have been prima facie obvious to apply Weiler et al's teachings of microarrays to Ulhmann et al's PNAs in order to increase hybridization specificity and affinity in microarray screening.

8. Claims 22 & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breipohl et al (US6,046,306 April 4,2000) in view of Weiler et al (NAR vol. 15 no. 14 pp. 2792-2799 1997).

The teachings of Breipohl et al are described previously.

Breipohl et al do not teach microarray.

Weiler et al teach the construction of PNA oligomer arrays for hybridization assays (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Weiler et al's teaching of microarrays to Ulhmann et al's PNA in order to construct oligonucleotide sensors. As Weiler et al states that the PNA may be used in arrays because the PNA provide high thermal stability and are instrumental for screening sequences (see page 2792-3). It would have been prima facie obvious to apply Weiler et al's teachings of microarrays to Ulhmann et al's PNAs in order to increase hybridization specificity and affinity in microarray screening.

9. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulhmann et al (Nucleosides & Nucleotides vol. 16(5&6) pp. 603-608 1997) in view of Manoharan et al (US6,043,352 March 28, 2000).

The teachings of Ulhmann et al are described previously.

Ulhmann et al do not teach binding to HA ras translation start or pharmaceutical composition.

Manoharan et al teach oligonucleotides used in pharmaceutical compositions with pharmaceutically acceptable diluent or carrier for diagnostics or therapeutics (see whole doc. esp. abstract and col. 8 line 45-50). Moreover they teach targeting Ha ras initiation translation region (see col. 16 lines 31-35). They also teach the use of PNAs (see col.3 lines 1-5). They teach modification with labels such as fluorescein and biotin(see col. 3lines 5-7).

One of ordinary skill in the art would have been motivated to apply Manoharan et al's teaching of binding to antisense inhibition with Ulhmann et al's PNAs in order inhibiting gene expression. As Manoharan et al teach that the oligonucleotides bind to target DNA or RNA for therapeutic antisense inhibition, which interfere with protein production ,increase maximum therapeutic effect and minimal side effects (see col. 1lines 14-26). It would have been prima facie obvious to apply Manoharan et al's teaching of antisense inhibition to Ulhmann et al's PNA's which provide increase hybridization efficiency in order to increase the inhibition efficiency of oligonucleotides to target DNA

SUMMARY

10. No claims allowed. The broad genus is taught by the prior art. However, the elected species (see response filed 2/19/03) is free of the prior art.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

JEFFREY SIEW
PRIMARY EXAMINER

April 14, 2003